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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,639

01/22/2004

Dmitry E. Protsenko

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02/20/2007

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EXAMINER

VRETTAKOS, PETER J

ART UNIT

PAPER NUMBER

3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/762,639

Applicant(s)

PROTSENKO ET AL.

Examiner

Peter J. Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-4-06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-40, 46, 47 and 49-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40, 46-47 and 49-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The action is final.

Claims 35-40, 46-47 and 49-56 are examined below. Claim 35 is the lone independent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-40, 46-47 and 49-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification does not sufficiently describe how an apparatus can comprise a means that causes **temporal** tissue change **and** a means that causes **permanent** tissue change. On its face, the statement is counterintuitive. Clarification is requested. (Also, does the Applicant mean to equate "temporally" with "temporarily"?)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

Art Unit: 3739

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz (6,770,070).

*Note: a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Also, a means-for claim including an intended use does not serve as a black-box structure negating the above argument. If a prior art structure used to reject a means-for limitation is **capable** of the intended use as indicated in the means-for limitation, then the prior art structure reads on the means-for limitation.*

Balbierz discloses:

35. An apparatus of electroforming tissue comprising:

means for creating stress in the tissue (see electrode 18 in figures 9 and distal end of device 16 in figures 5) to temporally define and maintain a predetermined shape of the tissue (the physical presence of the electrode may temporally physically displace the tissue while the electrode is adjacent the tissue); and

means for causing a current to flow in the tissue (power source 20 in figure 7 and electrode 18 in figures 9) while the created stress is present to permanently change (changes resulting from current application) shape of the tissue or material parameters of the tissue (inherent) without necrosis or ablation (**achieved through less power**

Art Unit: 3739

delivery than required for necrosis and ablation) (again, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim). Note: necrosis and ablation are the result of power thresholds being met during energy application. If power levels are keep below the ablation/necrosis power threshold, then no necrosis and ablation occurs but permanent changes can still occur to the tissue. The Office contends this as possible in Balbierz.

36. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for causing a direct current of a predetermined ("preset", col. 24:46) polarity (monopolar, bipolar changes in col. 24:46-53) to flow (power source 20) in the tissue to mediate the tissue. This claim includes intended use language.

37. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for mechanically applying force (see distal end of device 16 in figures 9) to the tissue to create external stresses applied to the tissue to temporally define and maintain a predetermined shape of the tissue.

38. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for changing material parameters (tissue puncturing edges - see

Art Unit: 3739

distal end of device 16 in figures 9) of the tissue to create internal stresses in the tissue to permanently change its shape to the predetermined shape.

39. The apparatus of claim 38 where the means for changing material parameters of the tissue comprises means for causing a direct current to flow (see electrode 18 in figures 9 and power source 20 in figure 7) in the tissue.

40. The apparatus of claim 35 further means for comprising monitoring (324 in figure 27; see col. 18:7-27) the stresses in the tissue and means for controlling (338 in figure 27, 350,329,346) the current flowing in the tissue according to the stresses therein.

46. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color of the tissue as caused by a chemical dye (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) disposed therein.

47. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) of the tissue as caused by electroplating a material thereon.

49. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying voltage pulses (power source 20) of the same

Art Unit: 3739

polarity to form a DC pulse train (intended use language) A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

50. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for applying a first sequence of voltage pulses of the same polarity (power source 20) and means for applying a second sequence (power source 20) of voltage pulses of the opposite polarity (power source 20) to form a complex DC pulse train (intended use language). A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

51. The apparatus of claim 50 where the means for applying a first sequence (power source 20) and means for applying a second sequence (power source 20) of voltage pulses provide a net charge cancellation when integrated over an application time (intended use language). A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

52. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for flowing direct current from a positive electrode to obtain tissue compression in the proximity of the positive electrode. The patent inherently includes tissue compression at the positive electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

53. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for flowing direct current from a negative electrode to obtain tissue lengthening in the proximity of the negative electrode. The patent inherently includes tissue lengthening at the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

54. The apparatus of claim 35 where the means for creating stress in the tissue comprises creating means for (16, 18, 20) tension, compression, shear or combinations thereof in the tissue. The patent inherently includes tissue lengthening at the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

55. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying a DC voltage (20) for a predetermined ("preset", col. 24:46) application time across two paired conductive elements (18 in figure 12) in contact with the tissue.

56. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined ("preset", col. 24:46) application time (350,329,346,338) across two paired conductive elements comprises means for (12 with 16) placing a solid conductive element (18) in contact with the tissue, including solid conductive elements composed of metals or conductive polymers (see col. 15:53-55).

Response to Arguments

Applicant's arguments filed 12-4-06 have been fully considered but they are not persuasive. The Applicant argues that the words stress and electroforming are not in Balbierz. However, no verbatim standard exists in patent law rejections. Instead, the Office presents art that is **capable** of electroforming, tissue compression, formation of complex DC pulse trains and causing stress (through a penetrating needle) in tissue due to structural equivalence as established above. The Applicant's arguments presuppose that the rejection of an apparatus claim must include art that expressly discloses the function and intended use of the prior art. This is incorrect. If the prior art is capable of the intended use of a claimed invention, then the prior art reads on the

Art Unit: 3739

claim. Balbierz discloses structure capable of creating stress in tissue and electroforming. No argument has been posited that precludes this statement. Furthermore, cell necrosis and ablation occurs when power thresholds are met in a tissue. The Office contends that by keeping the power levels below the ablation threshold, Balbierz is **capable** of causing tissue changes without ablation or necrosis.

Balbierz discloses an impedance sensor 324 that inherently monitors stress in tissue in the respect that a change in impedance of a tissue can reflect a change in the stress of the tissue. Balbierz discloses electrochemical, chemical and optical sensors **capable** of monitoring color.

Applicant's amendment **necessitated** the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

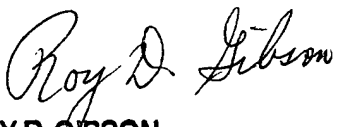

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
February 10, 2007



ROY D. GIBSON
PRIMARY EXAMINER